

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference 94756/3		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US01/50502	International filing date (day/month/year) 28 December 2001 (28.12.2001)	Priority date (day/month/year)	
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 35/78 and US Cl.: 424/725 514/783			
Applicant INTER AMERICAN UNIVERSITY OF PUERTO RICO			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 8 sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 23 June 2003 (23.06.2003)		Date of completion of this report 27 April 2004 (27.04.2004)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer Patricia Leith, F. K. Leith Telephone No. (571) 272-1600	

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☐ the international application as originally filed.
- ☒ the description:  
pages 1, 2, 5-7, 9-13, 15-22 and 24 as originally filed  
pages 3, 4, 8, 14 and 23, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the claims:  
pages NONE, as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages 25-27, filed with the letter of 22 April 2004 (22.04.2004)
- ☒ the drawings:  
pages 1-3, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☐ the sequence listing part of the description:  
pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/US01/50501

## V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. STATEMENT

Novelty (N)	Claims <u>2, 4-8, 10-11, 14-18 and 19-29</u>	YES
	Claims <u>1, 3, 9, 12 and 13</u>	NO
Inventive Step (IS)	Claims <u>2, 4-8, 10-11, 14-18 and 19-29</u>	YES
	Claims <u>1, 3, 9, 12 and 13</u>	NO
Industrial Applicability (IA)	Claims <u>1-29</u>	YES
	Claims <u>NONE</u>	NO

### 2. CITATIONS AND EXPLANATIONS

Please See Continuation Sheet

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>2, 4-8, 10-11, 14-18 and 19-29</u>	YES
	Claims <u>1, 3, 9, 12 and 13</u>	NO
Inventive Step (IS)	Claims <u>2, 4-8, 10-11, 14-18 and 19-29</u>	YES
	Claims <u>1, 3, 9, 12 and 13</u>	NO
Industrial Applicability (IA)	Claims <u>1-29</u>	YES
	Claims <u>NONE</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Please See Continuation Sheet

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

**V. 2. Citations and Explanations:**

Claims 1 and 3 lack novelty under PCT Article 33(2) as being anticipated by Amelio Mauro et al. (1998).

Amelio Mauro et al. (1998) disclosed stigmasta-3,5-diene and therefore anticipated these claims (Biosis Abstract).

Arguments are made that Amelio Mauro et al. did not teach stigmasta-3,5-diene in a carrier, however Amelio Mauro et al. taught that stigmasta-3,5-diene is indigenous to olive oil. Olive oil is considered a pharmaceutical carrier. Arguments are made that Amelio Mauro et al. did not teach a medicinal use for stigmasta-3,5-diene, however the claims are drawn to compositions. Stigmasta-3,5-diene in a carrier (olive oil) was known and therefore does not constitute a novel inventive concept. Arguments state that the Written Opinion stated that these claims were obvious but did not provide reasoning. If a claim lacks novelty under PCT Article 33(2), it automatically lacks an inventive concept under PCT Article 33(3) without further explanation. If a claim lacks novelty, it also lacks an inventive concept.

Claims 9, 10 and 13-lack novelty under PCT Article 33(2) as being anticipated by Morris et al. (1979).

Morris et al. taught benzyl salicylate in combination with agar (carrier) for combating microorganisms thereby anticipating the claims.

Arguments were made with regard to claim 12 which states 'galaxolide' and not benzyl salicylate. This inadvertant error has been corrected. Claim 10 is anticipated by Morris et al., while claim 12 is not. Arguments are made which indicate that benzyl salicylate was tested, but not taught by Morris et al. to be a preferred embodiment. However, the compositions were none-the-less known and therefore anticipated, regardless of whether or not Morris et al. specifically taught these compositions as preferred embodiments. Again, these are composition claims and the recitation of the 'use' of these claims do not attribute the claims novelty over the art.

Claims 9 and 12 lack novelty under PCT Article 33(2) as being anticipated by Unilever, N.V. (EP 0 499 304 A).

Unilever, N.V. disclosed a composition comprising benzyl salicylate and galaxolide (page 9).

Arguments are made that indicate that Unilever used benzyl salicylate and galaxolide merely as fragrance components and do not describe any medicinal efficacy in relation to these compounds. Again, these are composition claims. The compositions are known and therefore do not contribute any novelty over the art. The intended use for these compounds does not materially change the structure and function of the compounds, nor the structure and function of their combination into a composition. Therefore, the claims remain anticipated.

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

International application No.  
PCT/US01/50502

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Claims 2, 4-8, 10-11, 14-18 and 19-29 meet the criteria set out in PCT Article 33(2) and (3), because the prior art does not teach or fairly suggest the specific limitations in these claims.

Claims 1-29 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.